



California State Board of Pharmacy

1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Robert Graul, RPh, Chair
Bill Powers, Public Member
Robert Swart, PharmD
Shirley Wheat, Public Member
Andrea Zinder, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

ITEM B: Meeting Summary of the Legislation and Regulation Committee Meeting of July 10, 2008

FOR INFORMATION:

ATTACHMENT 1 contains the meeting summary from this committee meeting.

ITEM C: Request from the California Pharmacy Foundation for Clarification of Business and Professions Code section 4076.

FOR INFORMATION:

At the July 2008 Legislation and Regulation Committee Meeting, the committee received a request from Steve Gray, representing the California Pharmacy Foundation. The Foundation is requesting that the board sponsor legislation that will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient. One of the Foundation's primary focuses is on the reduction of medication errors and they believe that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient outcomes.

ATTACHMENT 2 is a written request from Dr. Steve Gray requesting that the board sponsor a legislative change as well as draft language for board consideration.

ITEM D: Update of the Committee's Strategic Plan for 2008/09.

FOR INFORMATION:

The committee did not submit any updates to its strategic plan for 2008/09. The committee's goals and objectives are provided in **ATTACHMENT 3**.

ITEM E: Fourth Quarterly Report on Committee Goals for 2007/08.

The update on the fourth quarterly report on committee's strategic goals for 2007/08 is included in **ATTACHMENT 4**.

Attachment 1

*Meeting Summary of the Legislation
and Regulation Committee Meeting of
July 10, 2008*



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES**

DATE: July 10, 2008

LOCATION: Department of Consumer Affairs
Hearing Room, Suite S 102
1625 North Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS

PRESENT: Robert Gaul, RPh, Chairperson
Andrea Zinder, Public Member
Robert Swart, PharmD
Bill Powers, Public Member
Shirley Wheat, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Tina Thomas, Analyst

Chairperson Robert Gaul called the meeting to order at 1:04 p.m.

Legislative and Regulatory Proposals for 2008

Board Sponsored Legislation for 2008

SB 1307 (Ridley-Thomas) Electronic Pedigree

This bill contains additional provisions to improve implementation issues involving serialization and electronic pedigrees. Specifically, it specifies that the serialization number must be contained in the electronic pedigree, staggers the implementation dates for e-pedigree compliance, allows for the grandfathering in of existing drug stock in the supply chain, and allows the board to establish criteria for inference requirements by regulation.

Due to further pending amendments to this bill, Chairperson Graul suggested further discussion be held at the July Board Meeting. The bill discussion is scheduled for July 24, 2008.

Ms. Herold reviewed items from the July 2008 Board Meeting Agenda and stated that the agenda will be mailed out tomorrow. She added that there is too much on the agenda on the first day of the meeting, therefore SB 1307 discussion will occur on the second day. The committee agreed to delay discussion.

SB 1779 (Omnibus)

Ms. Herold indicated that most provisions contained in the omnibus bill already been approved by the board. She indicated that there is one new provision, which is a proposed amendment to Section 4161 regarding non-resident wholesalers. Ms. Herold explained that, during the recodification process in 2004, the language was slightly changed. The language has caused an issue in relation to wholesalers who are not located in the state of California, but are moving product in California. During a recent cite and fine, the company went to hearing and insisted that they were exempt because they are not physically located within the California boundaries. This provision essentially will restore the provision to indicate that if a non-resident wholesaler is doing business outside of California, but moving products within California, they still have to be licensed in California. Ms. Herold added that the board has approved all other changes within the bill. She noted that the deputy attorney general who represented the board on this case helped draft the language.

Ms. Sodergren indicated that all other provisions of the bill were previously voted on. She noted that some of the provisions relating to the pharmacist-in-charge reporting requirements which were presented to the Business and Professions Committee were problematic and required additional clarification. As such, these were not included in this year's bill.

Ms. Herold explained that some senate members were not comfortable with the some of the provisions, and there was not sufficient time to address their concerns. Therefore those specific provisions will be addressed next year.

MOTION: To approve the revision to the language of the bill to include Business and Professions Code section 4161 and recommend the provision to the board.

M/S: BP/RS

Approve: 4 Oppose: 0

Legislation of Interest

Active Bills

AB 501 (Swanson) – Pharmaceutical Devices

Ms. Sodergren stated that this bill is sponsored by the Alameda County Board of Supervisors and would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to provide upon request of a consumer, a postage prepaid mail-back sharps container for safe disposal of the used device or a sharps container for storage and transport to a sharps consolidation location.

Chairperson Graul asked if there have been any changes since the board took the initial support position on the bill.

Ms. Sodergren responded that there have been amendments which relate to allowing alternative solutions of disposal for manufacturers to comply with regulation (versus mailback program exclusively).

Ms. Herold added that they've made the provisions less stringent.

Ms. Herold stated that she recently attended a "take back drug" seminar and noted that one of the discussions dealt specifically with syringes. Ms. Herold was concerned over the statistic provided at the seminar, indicating that there are one billion needles and syringes being disposed of in California annually.

Board position: Support

AB 865 (Davis) State Agencies: Live Customer Service Agents

Ms. Sodergren indicated that this bill would require specified state agencies to answer incoming phone calls within 10 rings by either a live customer service agent or automated telephone answering equipment which then must include an option to reach a live customer service agent.

Ms. Sodergren stated that board's phone tree did comply with the requirements of the bill. She added that the bill was recently amended and, according to DCA counsel, it no longer applies to the Board of Pharmacy.

Mr. Powers stated that he thought the bill was already a law.

Ms. Herold concurred and noted that the board strives to answer the phones within 10 rings and provide a "0" out option early on in the automated system.

Board position: Neutral

AB 1394 (Krekorian) Counterfeit: Trademarks

The committee was advised that this bill establishes stronger penalties for counterfeit trademarking, and further defines what would be considered counterfeit. The bill would remove the requirement that the sale of counterfeit mark be intentional and also make it a misdemeanor or a felony for a business entity to willfully manufacture, sell or knowingly possess for sale any counterfeit registered trademark.

Ms. Sodergren stated that the bill has been significantly amended, which includes penalties not being as strong as initially introduced.

Steve Gray (Kaiser Permanente) confirmed that it removes the issue of someone knowingly selling something that is counterfeit. He clarified that the bill removes the distinction between a pharmacist knowingly receiving counterfeit drugs versus knowingly dispensing (selling) a counterfeit drug. The concern is over the pharmacist intentionally selling it but unknowingly receiving the counterfeit drug, and being held responsible for that counterfeit drug.

Mr. Powers pointed out that Kaiser has not taken an opposed position on the bill.

Dr. Gray responded that they do have an organization analyzing the bill, but wants to ensure the board's understanding of the issue of distinction as he described.

Chairperson Gaul asked for clarification on Kaiser's position on the bill.

Dr. Gray stated that, as an organization they do not have a position. He stated however, that as a professional he is concerned as to whether the board understands the distinction that has now been made in the bill between holding a pharmacist liable for selling something they did not know was counterfeit.

Andrea Zinder asked Dr. Gray to indicate the revision in the bill which is of discussion.

Dr. Gray provided the language of the bill in discussion and referenced the analysis as well.

Chairperson Gaul recommended delaying any action or position on the bill in order to discuss the amended language further with counsel.

Ms. Herold asked if Kaiser would be involved.

Dr. Gray indicated that it is not probable at this point in the process.

Mr. Powers noted that the summary of the bill does not state the language in question. He also added that it is interesting that there is no opposition on the bill at all.

Committee Recommendation: None

AB 1436 (Hernandez) Nurse Practitioners

Ms. Sodergren indicated that this bill would revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized body approved by the Board of Registered Nursing. The bill would also expand the scope of practice to allow a nurse practitioner to perform comprehensive health care services as specified and is authorized to admit and discharge patients from health facilities, change a treatment regimen and initiate an emergency procedure in collaboration with healing arts practitioners.

Ms. Sodergren stated that the bill has now been expanded but still not discuss any expanded prescription authority.

Ms. Herold noted that the board wanted to be kept apprised of this particular bill, but the scope of practice lies with another agency.

Dr. Gray indicated that Kaiser nurse practitioners have stated that this bill strengthens the requirements of nurse practitioners (including national certification) and requires them to be personally accountable. He added that the bill also requires them to refer to a practitioner when it is in the best interest of the patient. Dr. Gray noted that this is particularly relevant in the case of pharmaceutical operations, as it was not clear in the law prior as to whether a nurse practitioner could refer a patient to a pharmacist who was practicing as part of a health care team. Dr. Gray stated that he feels the board should support of the bill for the reasons presented.

Chairperson Gaul asked for confirmation that Kaiser does not have a position on the bill.

Dr. Gray confirmed that Kaiser Permanente as an organization has not taken a position, but that pharmacy operations within Kaiser feel that the bill should be supported.

Chairperson Gaul asked if he believes Kaiser will take a support position.

Dr. Gray stated that he believes they will, but noted that California Medical Association is not necessarily supporting the bill.

Committee Recommendation: None

AB 1574 (Plescia) Surgical clinics: licensure

Ms. Sodergren reviewed the bill and indicated that the bill would expand the board's licensing authority to issue a clinic permit to surgical clinics that are Medicare certified or accredited by a recognized agency and require the board to perform periodic inspections and establish a self-assessment requirement.

Ms. Sodergren noted that similar provisions were in AB 2122 (Plescia). AB 2122 was held in Appropriations Committee as a suspense item and did not pass out of committee. She added that a recent court decision (the Capen decision) determined that the Department of Public Health (DPH) does not have jurisdiction and cannot issue licenses to surgical clinics that are in part or wholly-owned by physicians. She added that, because Business and Professions Code § 4190 only allows the Board of Pharmacy to issue clinic licenses to those licensed by DPH, there are several surgical clinics that are being impacted by the Capen decision.

Ms. Sodergren noted that the board has had a support position on two previous bills that also expanded the board's authority to issue clinic licenses.

Ms. Herold discussed two clinics that were unable to obtain licenses as needed because they do not fit the criteria of being licensed with DPH. She added that this bill would provide them with the means by which they can receive the benefits of receiving their drug supply at the wholesale acquisition cost and more importantly, can have commingled drugs under a centralized location and under centralized control. Without that, each individual practitioner must maintain their own drug supply or the clinic director has to purchase the drugs individually.

Ms. Zinder asked for clarification that Ms. Herold is recommending a support position.

Ms. Herold confirmed. She noted that there was a prior bill that was stalled in appropriations due to the cost of other provisions within the bill, not the cost of the provision being discussed here. She noted that the individual costs to the board would be offset by the licensee fees.

Dr. Swart asked whether the board has the authority and resources available in terms of staffing additional inspectors to regulate the bill. He noted that he is hesitant to support a bill if we are unable to provide staffing resources.

Ms. Herold responded that they are running a risk because the board does not necessarily have the additional staff to provide the inspections which the bill would require. She did note that they have attached a fiscal to the bill indicating that an additional inspector will be needed in order to conduct annual inspections to those entities that are not regulated under another agency. The board staff does feel that they will be successful in obtaining the additional staff through the budget process because of the inspection requirements of the bill, but it is not definite.

Ms. Wheat asked if such language authorizing the additional staff is included in the language.

Ms. Herold responded that there is no language in the bill. The board has provided a fiscal analysis, and that language is not addressed until after the bill is enacted.

Mr. Powers confirmed that there is a fiscal analysis by the Committees and they expect this bill to go through. He confirmed that the 400 pharmacies affected would offset the cost by paying fees, and that the income should match the expenses.

Ms. Herold added that they would need to find another way to augment inspector staff (via budget change proposal) as current staff is tapped out.

Ms. Wheat asked how surgical clinics currently provide drugs.

Ms. Sodergren explained that each practitioner carries his or her own drug supply.

Greg Hurner (State and Consumer Services Agency) stated that they are not the primary on this bill, but that there are a couple of different approaches to address the legal case, and there are some concerns about dueling approaches to this, and that this may be the approach they have concerns with.

Ms. Sodergren responded that she believes DPH has also suggested a legislative fix, but doesn't believe they have an author.

Mr. Hurner stated that there are a couple of varying approaches on solutions to address the issue, and there are some concerns to the approach in discussion.

Ms. Sodergren provided clarification in stating that she believes DPH is looking at their fix to the Capen decision separately from the board's issue at hand. She indicated that the issue for DPH is that they can no longer issue or regulate a surgical center and is looking for a legislative fix to that which is independent of what the Board of Pharmacy is addressing. The board is only looking at who is going to maintain a drug supply or whether they will allow commingling of the drug supply.

Motion: To support AB 1574

M/S: AZ/BP

Support: 4 Oppose: 0

AB 1587 (De La Torre) Personal Information: pharmacy

This bill would exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

Ms. Sodergren advised that, according to the sponsor, this bill would not be moved this year.

Committee Recommendation: None

AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency

Ms. Sodergren stated that the bill would specify that, for purposes of furnishing dangerous drugs and devices during an emergency, a pharmacist is not required to await a declaration of emergency as long the declaration is reasonably anticipated due to the severity of the emergency or natural disaster.

Board Position: Support

SB 963 (Ridley-Thomas) Regulatory Boards: sunset review

Ms. Sodergren indicated that this bill replaces the process whereby a sunsetted board becomes a bureau in the Department of Consumer Affairs (DCA) with reconstitution of the board's members, and specifies other reporting requirements.

Ms. Sodergren advised that the bill has been significantly amended, and that the bill is still a work in progress. She stated that additional amendments are anticipated. She added that it might be premature to take a position at this time.

Ms. Zinder asked what the board's status is in the mean time.

Ms. Herold responded that, if you we do not get an extension, the Board of Pharmacy has one more year to exist as a board and will sunset. She added that next year we will have to have this bill or another bill to move the date back to avoid being sunsetted. Ms. Herold stated that there is a meeting tomorrow between executive officers, the Department and lobbyists to discuss amendments. Ms. Herold requested the board to allow the meeting to take place in order to provide some direction on a decision. She pointed out that the sunset review process, which was of value many years prior, does not receive much legislative interest anymore.

Mr. Powers confirmed that this is a Committee bill.

Committee Recommendation: None

SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

Ms. Sodergren advised that this bill would create an electronic pedigree task force to provide the board with updates regarding industry readiness on the implementation of the pedigree requirements as well as to submit an annual report to the board and specified legislative committees.

Ms. Herold noted that the fiscal cost to the board for this task force would be \$150,000, spread over a couple of years.

Dr. Swart recommended to take either no position or oppose, as we already have significant information and updates being provided by the industry during the Enforcement Committee meetings, and does not feel the redundancy is necessary.

Board Position: None

SB 1441 (Ridley-Thomas) Healing Arts Practitioners: substance abuse

Ms. Sodergren stated that this committee or the board has not previously reviewed this bill. The bill would create the Substance Abuse Coordination Committee with the Department of Consumer Affairs to develop uniform and specific standards that each healing arts board would be required to use in dealing with substance-abusing licensees.

Ms. Sodergren noted that the Board of Pharmacy does not use a Diversion Evaluation Committee structure currently being used in other boards. Rather, the board has a committee consisting of a consultant, supervising inspector and staff manager that monitor the board informal and formal referrals. She stated that the intent of the legislation is to strengthen diversion programs and review the Board of Pharmacy's diversion program as well as others within DCA in order to determine a consistent and uniform program structure, which will better protect the public. Ms. Sodergren added that several of the boards listed within this legislation are being given a program manager to make treatment recommendations for the individuals in the program. She stated that the board already uses a program manager to complete many of the functions detailed in the legislative proposal. She added that the legislation would also create a committee within the DCA which would include all of the Executive Officers' involvement in establishing guidelines for evaluating criteria and address issues of relapses.

Ms. Herold explained the goal, which is to strengthen the department's diversion program overall and to provide parameters to make them more centralized. She added that one of outcomes is that the board may be adopting a program that will have very similar disciplinary guidelines to the board's program. Ms. Herold pointed out that the board's current program is very strong, and that recently one of the participants of the program sent a letter to the Senate Business and Professions Committee indicating that the Board of Pharmacy's program is too stringent.

Mr. Powers feels that they should take no position at this time.

Committee Recommendation: None

The committee was advised that information on inactive bills was provided in the packet.

Board Approved Regulations – Awaiting Notice (Status Update)

Repeal of 16 CCR §§ 1716.1 and 1716.2 and amendment to 16 CCR § 1751-1751.8 and adoption of 16 CCR §§1735-1735.8 – Pharmacies that Compound

The committee was advised that current pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. Ms. Sodergren pointed out that this proposal would establish guidelines to provide uniformity in compounding for California consumers.

At the January 2008 Board Meeting, the board conducted a regulation hearing to hear testimony about the regulation proposal that establishes requirements for pharmacies that compound medications. As a result of this regulation hearing, the board voted to complete a 15-day notice with revised language to address some of the written comments received and oral testimony provided.

Given the significant amount of comments submitted and testimony provided, staff recommended and the board voted to withdraw the rulemaking to allow time to further refine the draft language.

Ms. Sodergren noted that the staff planned to notice the revised rulemaking in advance of the July 2008 Board Meeting, however because of conflicting priorities within the department's legal office, were unable to submit by the deadline to allow for action by the board in July. Staff will notice the rulemaking for action by the board at the October 2008 Board Meeting.

Chairperson Graul asked if there have been any significant changes in the proposed language.

Ms. Sodergren stated that there have been no significant changes and that the board previously approved the language.

Dr. Swart clarified that the regulation language does not affect general compounding practices and individual compounding situations.

Ms. Herold stated that there have been a number of amendments and modifications to the proposed language over the last couple of years and that it should now be in its final form. She stated that at the April Board Meeting the action taken was only an effort to make it a clean rulemaking process. She added that legal must review the final version before it leaves the department and there was a delay in that process.

Bill Swanger (CSHP) asked if there was a timeline for filing of the bill.

Ms. Herold responded that, since we are starting over, it is unknown.

Ms. Sodergren stated that it would most likely be in August, as the 45-day comment period will be over in advance of the October Board Meeting.

Proposed Addition to 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Ms. Sodergren stated that the adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The committee was advised that the draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Mr. Powers asked if the regulation proposal is moving forward.

Ms. Herold responded that they are recruiting for a staff manager and this will be one of their duties. She added that this is for information only at this stage.

Proposed Amendment to 16 CCR §1780 – Update the USP Standards Reference Material

The committee was advised that CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

Ms. Sodergren indicated that at the April 2007 Legislation and Regulation Committee Meeting, the committee heard public comment warning the board of unintended consequences by referencing the current USP Standards Reference Materials and was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather requested input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material.

Ms. Sodergren stated that to date board staff has not received any additional information or concerns about pursuing this change and is seeking guidance from the committee on whether to pursue this regulation change.

Dr. Gray confirmed his prior suggestion to the board to delay moving forward in order to review any significant changes and their impact. He stated that he thought someone from Kaiser had already submitted the input. Dr. Gray said that he would go back and ask for the information to be provided to the board.

Ms. Herold noted that there is a concern over this becoming an archive issue and having difficulty in obtaining a specific prior USP version. She stated that they are waiting for input from the subcommittee before moving forward.

Dr. Gray reiterated he would go back and request information again.

Proposed Adoption of 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Ms. Sodergren advised that section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

The committee was advised that the proposed regulation would specify the criteria the board uses to evaluate these agencies.

At the July 2007 Board Meeting, the board voted to move this proposal.

Ms. Herold stated we should not expect to see the final ruling until January 2009.

Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

Ms. Sodergren advised that at the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

The committee was advised that the recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Ms. Sodergren stated that the board has previously approved the language and we are awaiting notice.

Board Adopted Regulations

Ms Sodergren stated that at the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR 1760 – Disciplinary Guidelines. She stated that during discussion at this Board Meeting, counsel recommended that the board strengthen the response to comments submitted during the written comment period. Ms. Sodergren added that staff is awaiting further explanation from counsel for inclusion in the rulemaking. Upon receipt of this information, staff will move forward to compile the rulemaking file to submit for administrative review.

Proposed Regulation Language for Committee Consideration

Amend Title 16 CCR section §1773 – Disciplinary Conditions of Probation of a Pharmacist and Adopt Title 16 CCR §1773.5 - Ethics Course for Pharmacists

The committee was advised that at the October 2007 Board Meeting, the board voted to pursue a regulation proposal to develop an ethics course for pharmacists, modeled after the program used by the Medical Board of California. She added that a subcommittee considered program alternatives and the board voted on a program similar to that used by the Medical Board.

The committee was also advised that, based on the results of the committee's recommendation, language could be considered for approval by the full board at the July 2008 Board Meeting.

Ms. Sodergren provided background on the development by the board of an ethics course for pharmacists similar to the ethics course in place with the Medical Board.

Ms. Sodergren advised that, in order for the board to establish this program, they would need to put the parameters of the program into regulation as it would be requiring pharmacists to comply as part of their terms and conditions of probation. She stated that section 1773 adds in the completion of the ethics course as a possible requirement for discipline, and that section 1773.5 details what that course would need to look like. Ms Sodergren noted that board reviewed ethics program conducted by the Institute for Medical Quality who provided a presentation to the board.

Ms. Herold stated that the board needed to draft language, and noted that the language is very similar to that of the ethics course established with the Medical Board.

Motion: To support the amendments of 16 CCR §1773 – Disciplinary Conditions of Probation of a Pharmacist and to adopt Title 16 CCR §1773.5 – Ethics Course for Pharmacists.

M/S: BP/AZ

Approve: 4

Oppose: 0

Amend Title 16 CCR section § 1715 – Self Assessment Forms

The committee was advised that board staff would begin work to update the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in section 1715, the board must pursue a regulation change to require use of the new form.

The committee was also advised that, based on the results of the committee's recommendation, language could be considered by the full board at the July 2008 Board Meeting.

Ms. Sodergren indicated that this is proposed language that the committee has not seen. She explained that the board needs to vote to pursue the regulation change, which can be done as a section 100 change. She added that the proposal changes revision date and then self-assessment form will be updated.

Ms. Herold clarified that the requirement is that the self-assessment form be completed every odd-numbered year. Thus, this is the time the process needs to be started in order to have the revisions ready for 2009. She explained that the proposal is in the current form because we need to wait until October to know what new pharmacy law will enacted in January 2009.

Mr. Powers stated that there is only a date change.

Ms. Herold confirmed, and explained that we don't know what bills will come into place in pharmacy law between today and the time the board will be asked to take a position.

Dr. Swart clarified that we would be approving board staff to make any changes that may occur between now and January 2009, with the discretion of the Executive Officer.

Ms. Herold added that the board would be directing the staff to make sure that the self-assessment form is kept current, and that it is appropriately updated for pharmacists to conduct the self-assessment on July 1, 2009.

Dr. Gray asked if that means industry will get a chance to see the language of the self-assessment form or is this direction for the board to move forward.

Ms. Sodergren explained that a section 100 change is not noticed, as a standard rulemaking would be, as this is only a technical change. She added that this is a form incorporated by reference, which is pharmacy law restated with check boxes, and pursued this as a technical change.

Dr. Gray asked if there would be an opportunity to review the revised form before final adoption and allow for comment or input.

Ms. Herold confirmed.

Dr. Gray suggested changing the format to add numbering by section rather than bullet points, in order to provide for easier discussion and specify changes more clearly.

MOTION: To support the amendment to Title 16 CCR Section 1715

M/S: SW/BP

Support: 4 Oppose: 0

Public Requests for Future Legislation and Regulatory Proposals

Dr. Gray speaking on behalf of the California Pharmacy Foundation advised the board that he is active in a new campaign to prevent medication errors, with a specific focus on the elderly and the “sandwich generation” (those caring for both elderly parents and their children). He stated that this group of consumers needs significant attention, as there is a lack of information on dosing for them. Dr. Gray stated that one of the top three findings from the campaign’s study is that the prescription label would be most helpful if it indicated what the prescription was specifically for (i.e. heart, foot, earache, pain, swelling). He indicated research has been done to find out what the pharmacist’s view was as to whether they should or could conduct that type of labeling. He noted that the results were interesting because of the wide generation of pharmacists, reflecting how long they’ve been in practice and when they were trained. Dr. Gray stated that it was not well understood amongst the pharmacists as to whether it is their responsibility to know what the issue is and whether the prescription is appropriate, etc. Dr. Gray referred to language with SB 1779 (Omnibus bill) which states that the pharmacist is required to provide the information as to what the prescription is for if it is requested. He indicated that this language is being interpreted by some pharmacists to indicate that they cannot place a label stating what the prescription is for unless the customer asks them to do so. Dr. Gray reiterated that a significant amount of errors are a result of the customer not being sure of what their prescription is for. He added that the issue is more significant with elderly consumers because of their higher usage of various prescriptions. Dr. Gray suggested that the committee consider whether there may be a need to propose a change in that section of the language to make it clear that pharmacists have the discretion to include on the label what a prescription is for.

Mr. Powers asked how the pharmacist is supposed to find out what the prescription is for.

Dr. Gray responded that pharmacists are now trained and required to be competent in consultation by education and law. He added that pharmacists cannot competently consult unless they know what the prescription is for. He stated that they will typically talk to the patient or prescriber, check their medical record, etc. Dr. Gray noted that some pharmacists have been using this point as an excuse.

Mr. Powers pointed out that the consultation occurs after the prescription has been prescribed and filled.

Dr. Gray responded that pharmacists might have to talk to the patient before they put the label on. He reiterated this as being one of the top three causes of medication errors. Dr. Gray also referred to the SB 472 committee and their efforts to find a solution that will allow the information to be placed on label.

Mr. Powers suggested going before the medical board to suggest that the doctor indicate what the drug is for within their prescription.

Dr. Gray stated that they have tried, but have not been successful. He stated that there is nothing in the Medical Practices Act that specifies in detail what has to be on a prescription. Everything that has to do with prescriptions is under pharmacy law.

Mr. Powers asked for clarification on whether this is already been addressed by the task force.

Dr. Gray noted that the task force has stated that they do not have authority over this.

Ms. Wheat commented on the handout provided with the prescription by most pharmacies.

Dr. Gray responded that the patient needs to know what it is for them specifically in "simple human terms".

Dr. Swart agreed with Mr. Powers' concern in delaying prescription fills if pharmacists would need to go back to adding information on the prescription after talking to each patient.

Dr. Gray reiterated the issue at hand which is that, because of training and law, pharmacists have thought they weren't authorized to place the information on the label.

Chairperson Graul asked for clarification of the proposal.

Dr. Gray stated that his proposal is to change the labeling statute to make it clear that pharmacists are authorized to place the information on the label or to require the information to be added to the label.

Ms. Herold advised that the SB 472 board task force is in the process of collecting surveys from the public on input for the labels. She indicated that the board staff would bring the data to the July Board Meeting. Ms. Herold stated that one comment has been consistent in surveys so far, and that is that they want the information on the label of what the drug is for. She confirmed that SB 472 is not empowered to change the requirements of the legislation. She noted, however, that there is the ability to add an

element to the label, such as to leave a space on the label and set it up as a standardized component without having to get a legislative mandate behind it. Ms. Herold reiterated that there is consumer support behind this need. She added, however, that every time a similar bill goes to legislature, it does not get far.

Dr. Gray stated that previous legislation has failed because of privacy issues between the doctor and patient.

Chairperson Graul asked that the item be added to the Board Meeting agenda.

Ms. Herold stated that the item will be added to the July Board Meeting, and asked Dr. Gray to provide language for the proposed amendment to the board by July 15.

Dr. Gray agreed to provide the language.

Ms. Herold noted that there would be two speakers at the July Board Meeting presenting on the subject of medication errors. In addition, there will be a presentation from the Department of Public Health to discuss their requirements of data submitted from the hospitals in relation to medication errors.

Public Comment for Items Not on the Agenda

There were no public comments.

The meeting was adjourned at 2:12 p.m.

Attachment 2

- *Letter from Dr. Steve Gray*
- *Draft language*

Personal Memorandum 3 pages

To: V. Herold, Exec. Officer California State Board of Pharmacy

From: Steven Gray, PharmD, JD

14 July 2008

As a concerned individual citizen and pharmacist I believe that the Board of Pharmacy should sponsor a legislative change in 2009 that would facilitate having pharmacists place the "purpose" of the medication on the label that is affixed to every prescription container that is dispensed to/for a patient. It is essential that that this "purpose" be an indication of "what the medication is for" in layperson terms and NOT the "diagnosis" or the "indication" as used by medical and pharmacy professionals. For example, if the patient has bone cancer and is being treated for pain, the label would not list the type of cancer or even that the patient has "cancer". The label would just read that the medication is "for pain". This not only makes it understandable to most patients but it resolves most concerns about patient privacy that have been often raised to deflect previous legislation.

I submit that it has been well documented that having "what the medication is for" on the prescription label would significantly prevent medication errors not only in dispensing, but especially in the home or place of therapy by the patient, his/her family or other caregivers. Having this information was so identified in the "SCR 49" report a year or so ago and during the discussions among the public regarding passage and implementation of last year's SB472.

I believe the legislation should include some "findings" by the Legislature about the problems of medication errors, health literacy, therapy compliance/adherence and their impact on rising costs and lower affordability and coverage; and about how this label requirement is important to their prevention. Such findings about error prevention are supported in the report to the Legislature by the SCR 49 group and in various national publications.

As you know similar legislation has been proposed before but objected to on various grounds, such as the patient's privacy, the unavailability of "diagnosis" information from the prescriber, reluctance by pharmacists or pharmacy organizations to incur liability for pharmacist's professional judgment, reluctance to change pharmacy work flow, etc. In balancing these considerations, most consumer groups and medication quality professionals have concluded that the benefits to patient safety, medical care quality and overall efficiency far outweigh such concerns. I believe that the evidence is now sufficient to make it imperative for the Board to take this action in spite of past or future persistent opposition.

I have submitted herein some recommended language changes to the Business and Professions Code that should be all that is needed. I do not believe that amending sections of the code for physician practice or regarding the practice of other prescribers is necessary and in fact I believe such proposed modifications would only hinder enactment. It is the pharmacy sections of the B&P Code that list label and prescription requirements that dictate the actions of all prescribers.

Pharmacists have sufficient training to determine "what the medication is for" in the vast majority of cases. Most of the time when a patient

presents 1 or 2 prescriptions at the pharmacy, the patient knows what the medication is for or it is obvious from the type of medication. Actually only a very few medications have such varied uses that the pharmacist would need to seek clarification from the prescriber, the patient's medical record or other sources. Note again: I am NOT proposing listing the "diagnoses" or "indications".

The value of listing the "purpose" on the label is that it is patient specific and medication specific, unlike listing general indications on "Patient Package Inserts" or other handouts, etc. Also, it is when the patient gets home and gets confused about the purpose of the latest medications and all the other medications that serious medication errors begin or, because of the confusion, problems in therapy compliance/adherence happen. For the few instances where the pharmacist may need more information, they have reasonable access to the prescriber and/or the patient's medical record, either directly or indirectly through the prescriber's staff or the patient's caregivers, e.g. in an SNF or Hospice, etc. In fact it has been widely promoted by the Board and the standards of practice that a pharmacist already needs this "purpose" information in order to properly review the patient's prescription profile and provide prescription consultation.

Suggested Statute Changes: Additions are underlined and deletions have a "strike through" in the standard amendment manner. If you need clarifications, please contact me.

Amend Business and Professions Code section 4076.

"4076(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph

(5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) Except as requested by the patient or the patient's personal representative or by the prescriber, or except where the information is not immediately available and the dispensing pharmacist has documented in the prescription record why in his/her professional judgment a delay in dispensing in order to obtain the information would cause significant suffering by the patient or a clinically significant deterioration in treatment effectiveness, The the condition purpose for which the drug was prescribed, if requested by the patient and whether or not the condition purpose is indicated on the prescription by the prescriber. The pharmacist may use his/her professional judgment to determine how to describe the purpose on the prescription label whether indicated by the prescriber or not and the prescriber will incur no liability for the exercise of such judgment by the pharmacist. As used in this section the term "purpose" shall mean a statement in patient-oriented or layperson terms of "what the medication is for", which shall not necessarily be a statement of the patient's medical "condition" or "diagnosis" or the drug's "indication" as those terms are used by medical and pharmacy professionals.

(11) (A) ~~Commencing January 1, 2006, the~~ The physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section

2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice."

Attachment 3

Committee's Strategic Plan for 2008/09

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes
Tasks:	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date (SB 1476). 2. Sponsor legislation to update pharmacy law (SB 1475). 3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408). 4. Secure statutory standards for pharmacies that compound medications (AB 595) 5. Secure implementation of e-pedigrees on prescription drugs dispensed in California (SB 1476)
Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes
Tasks:	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)) 3. Make technical changes in pharmacy regulations to keep the code updated <ul style="list-style-type: none"> Section 1706.2 criteria for abandonment of files Section 1775.4 contested citations Section 1709.1 designation of pharmacist-in-charge Section 1780 standards for wholesalers Section 1780.1 standards for veterinary food animal drug retailers Section 1781 Designated Representative certificate Section 1786 Designated Representative 4. Notice of posting regarding electronic files (section 1717.2) 5. Disciplinary guidelines revision and update (section 1760) 6. Self-assessment of a wholesaler by the designated representative section (1784) 7. Exempt the address of records of interns from display on the board's Web site (section 1727.1) 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission 9. <u>Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2)</u>

Objective 3.3	Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed
Tasks:	

Attachment 4

Fourth Quarterly Report on Committee Goals for 2007/08

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<ol style="list-style-type: none"> Secure extension of board's sunset date. <i>Sept. 30, 2006: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</i> <i>June 2007: SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</i> <i>July 2008: SB 963 (Ridely-Thomas) is amended to alter the sunset review process.</i> <i>Board staff attend a stakeholders meeting with committee staff to discuss amendments.</i> Sponsor legislation to update pharmacy law. <i>Sept. 30, 2006: Governor signs SB 1475 containing provisions that:</i> <ol style="list-style-type: none"> <i>Allow a check-off box on electronic prescriptions that if marked by a prescriber, would prevent generic substitution at a pharmacist's discretion (B&P 4073).</i> <i>Clarify requirements for reporting to the board when a licensee is impaired to the extent it affects the licensee's safe practice or who has stolen or diverted drugs (B&P 4104).</i> <i>Establish the authority to issue a temporary sterile injectable compounding license following a change in ownership (B&P 4127.8).</i> <i>Exempt government-owned wholesalers from having to post a \$100,000 bond (B&P 4162).</i> <i>Exempt drug manufacturers who hold a biologics license application from the FDA from having to post a \$100,000 bond otherwise required for nonresident wholesalers (B&P 4162.5).</i> <i>Make technical changes in the licensure requirements for clinics (B&P 4180 - 4182, 4190 - 4192).</i> <i>June 2007: Senate Business and Professions Committee omnibus bill (SB 1048) is amended to include board provisions that:</i> <ol style="list-style-type: none"> <i>Revise section to include schedule IV controlled substances to the CURES reporting requirements for hospitals. (B&P 4068)</i> <i>Allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded. (B&P 4084)</i> <i>Change the term "exemptee" to "designated representative." (B&P) 4101</i> <i>Revise section to specify temporary license fee of \$550. Current law does not specify the temporary fee. (B&P 4160 (f) & 4161 (k))</i> <i>Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475. (B&P 4162 & 4162.5)</i>

	<p>(f) <i>Change in the name of the exam to more accurately reflect the requirements described in B&P 4200.2. The new name will be the "California Practice Standards and Jurisprudence Examination for Pharmacists" (CPJE). (B & P 4200, 4200.1 & 4200.2)</i></p> <p>(g) <i>Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license. (B&P 4208)</i></p> <p>(h) <i>Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies. (B&P 4314 & 4315)</i></p> <p>Oct. 2007: <i>Governor signs SB 1048 (Chapter 588, Statutes of 2007) containing board omnibus provisions.</i></p> <p>Oct. 2007: <i>Legislation and Regulation Committee considers omnibus provisions for introduction in 2008. Four types of changes are discussed.</i></p> <p>(1) <i>Omnibus changes specific to the PIC and DRC requirements</i></p> <ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i> <p>(2) <i>Omnibus changes to allow for the use of mobile pharmacies</i></p> <ul style="list-style-type: none"> • <i>Section 4062 Furnishing Dangerous Drugs During an Emergency.</i> • <i>Section 4110 License Required, Temporary Permit Upon Transfer of Ownership.</i> <p>(3) <i>General omnibus changes</i></p> <ul style="list-style-type: none"> • <i>Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.</i> • <i>Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory</i> • <i>Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.</i> • <i>Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i> • <i>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</i>
--	---

	<p>(4) Omnibus changes based on recodification of Business and Professions Code section 4052</p> <ul style="list-style-type: none"> • Section 733 – Dispensing Prescription Drugs and Devices • Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities • Section 4040 – Prescription; Content Requirements • Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist • Section 4060 – Controlled Substance – Prescription Required, Exceptions • Section 4076 – Prescription Container – Requirements for Labeling • Section 4111 – Restrictions on Prescriber Ownership • Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner • H&SC 11150 – Persons Authorized to Write or Issue a Prescription <p>Jan. 2008: Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.</p> <p>Board approved language for omnibus bill.</p> <p>April 2008: Some provisions of omnibus bill not included:</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4362 – Entry Into Pharmacists Recovery Program. <p>3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).</p> <p>Sept. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.</p> <p>4. Secure statutory standards for pharmacies that compound medications (AB 595).</p> <p>Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.</p>
--	--

	<p>5. Secure implementation of e-pedigrees on prescription drugs dispensed in California (SB 1476). <i>Sept. 30, 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.</i></p> <p>6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction. <i>AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects. AB 249 (Eng) Healing Arts: Settlement Agreements. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure. AB 1025 (Bass) Professions and Vocations: Denial of Licensure. SB 472 (Corbett) Prescription Drugs: Labeling Requirements. SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund. SB 606 (Scott) Pharmaceutical Information: Clinical Data Trial. SB 963 (Ridely-Thomas) Regulatory Boards: Operations. SB 966 (Simitian) Pharmaceutical Drug Disposal.</i></p> <p><i>Oct. 2007: Governor signs the following: AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects. SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements. SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.</i></p> <p><i>Oct. 2007: Governor vetoes the following: AB 249 (Eng) Healing Arts: Settlement Agreements. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure. AB 1025 (Bass) Professions and Vocations: Denial of Licensure. SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</i></p> <p><i>Jan. 2008:</i></p> <ol style="list-style-type: none"> 1. AB 501 (Swanson) Pharmaceutical Devices 2. AB 865 (Davis) State Agencies: Live Customer Service Agents 3. AB 1436 (Hernandez) Nurse Practitioner Scope of Practice 4. AB 1587 (de la Torre) and SB 843 (Calderon) Medical Information Marketing 5. SB 963 (Ridley Thomas) Regulatory Boards: Sunset Review 6. AB 1 X (Nunez) Health Care Reform <p><i>April 2008:</i></p> <ol style="list-style-type: none"> 1. AB 501 (Swanson) Pharmaceutical Devices 2. AB 865 (Davis) State Agencies 3. AB 1394 (Krekorian) Counterfeit: Trademarks 4. AB 1436 (Hernandez) Nurse Practitioners Scope of Practice 5. AB 1587 (de la Torre) Personal Information: Pharmacy 6. AB 2122 (Plescia) Surgical Clinics: licensure 7. SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review 8. SB 1270 (Cedillo) Pharmacy: dangerous drugs and devices pedigree 9. SB 1594 (Steinberg) Bleeding disorders clotting products
--	--

	<p>7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.</p> <p><i>March 2007:</i> Licensing Committee considers and approves concept. More work is required.</p> <p><i>June 2007:</i> Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.</p> <p><i>Sept. 2007:</i> Licensing Committee forwards to full board legislative proposal.</p> <p><i>Oct. 2007:</i> Board approved draft legislation</p> <p><i>Nov. 2007:</i> Staff meeting with stakeholders to elicit support for the proposal.</p> <p><i>Dec. 2007:</i> Staff develop fact sheets and work with experts in immunizations.</p> <p><i>Jan. 2008:</i> Seeking coalition to support initiative. Will pursue proposal in 2009.</p> <p>8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.</p> <p><i>Oct. 2007:</i> Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.</p> <p><i>Oct. 2007:</i> Subcommittee of the board is created to facilitate changes to regulation. Members include: Dr. Schell, Chair; Dr. Ravnan; Dr. Conroy; Dr. Swart; and President Powers.</p> <p><i>Jan. 2008:</i> Shirley Wheat added to the subcommittee.</p> <p><i>Apr. 2008:</i> First public forum held in Fremont.</p> <p><i>May 2008:</i> Staff develop survey form to distribute to consumers to solicit input Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.</p> <p><i>June 2008:</i> Staff attend community events, interview attendees about prescription label and distribute surveys.</p> <p><i>July 2008:</i> Staff attends community events, interview attendees about prescription label and distribute surveys.</p>
--	--

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> <p>1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8).</p> <p><i>Aug. 2006: Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.</i></p> <p><i>Nov. 2006: Rulemaking file submitted to the Office of Administrative Law.</i></p> <p><i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i></p> <p>2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)).</p> <p><i>Aug. 2006: Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.</i></p> <p><i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i></p> <p>3. Make technical changes in pharmacy regulations to keep the code updated.</p> <p><i>Dec. 2006: Board notices regulation for 45 days of public comment.</i></p> <p>Section 1775.4 contested citations</p> <p>Section 1706.2 criteria for abandonment of files</p> <p><i>Jan. 2007: Board adopts regulations.</i></p> <p>Section 1775.4 contested citations</p> <p>Section 1706.2 criteria for abandonment of files</p> <p><i>Feb. 2007: Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.</i></p> <p>Section 1775.4 contested citations</p> <p>Section 1706.2 criteria for abandonment of files</p> <p><i>April 2007: Section 1775.4 contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i></p> <p><i>June 2007: Changes to 1706.2 take effect following approval by the Office of Administrative Law.</i></p> <p>4. Repeal the requirement to post a notice regarding electronic files (section 1717.2).</p> <p><i>July 2006: Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.</i></p> <p><i>Oct. 2006: Board approves regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration review.</i></p> <p><i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i></p> <p>5. Revise and update Disciplinary Guidelines revision and update (section 1760).</p> <p><i>Aug. 2006: Final changes to Disciplinary Guidelines being compiled by staff.</i></p> <p><i>Dec. 2006: Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.</i></p> <p><i>June 2007: Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.</i></p> <p><i>Sept. 2007: Enforcement Committee approves Disciplinary Guidelines and recommends board approval.</i></p> <p><i>Oct. 2007: Board approves Disciplinary Guidelines for 45-day comment period.</i></p> <p><i>Feb. 2008: Regulation released for 45 days of public comment.</i></p> <p><i>April 2008: Board Adopts regulation.</i></p>

	<p>6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>July 2006:</i> Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting. <i>Oct. 2006:</i> Board approves regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration review. <i>April 2007:</i> Office of Administrative Law approves rulemaking. Regulation takes effect. <i>May 2007:</i> Wholesalers are notified of this requirement.</p> <p>7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). <i>Sept. 2006:</i> Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</p> <p>8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006:</i> Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007. <i>June 2007:</i> Board staff submit rulemaking file to the California Building Standards Commission.</p> <p>9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). <i>Feb. 2007:</i> Board notices regulation for 45 days comment period. <i>April 2007:</i> Board considers comments submitted during public comment period and modifies text regulation to reflect comments. <i>May 2007:</i> New section 1707.2 released for 45 days of public comment. <i>July 2007:</i> Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review. <i>Sept. 2007:</i> File submitted to the Office of Administrative Law for review. <i>Oct. 2007:</i> Office of Administrative Law approves rulemaking. <i>Nov. 2007:</i> Regulation changes takes effect. <i>Nov. 2007:</i> Staff solicits design submissions from graphic designers. <i>Jan. 2008:</i> Communication and Public Education Committee make recommendations on design submissions.</p>
--	--

10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.

June 2007: Submitted the following Section 100 changes:
Section 1707 – Waiver Requirements for Off-Site Storage of Records.
Section 1709.1 – Replace the term “Exemptee-in-Charge” with “Designated Representative-in-Charge”.
Section 1715 – Self-Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law.
Section 1719 – Pharmacy Practice.
Sections 1780.1 and 1781 – Replace the term “Exemptee” with “Designated Representative”.
Section 1786 – Return of Exemptee Certificate.
Section 1787 – Authorization to Distribute Dialysis Drugs and Devices.
Section 1790 – Assembling and Packaging.
1793.8 – Update regulation reference to recodified Business and Professions Code section 4052.

Aug. 2007: Staff withdraw Section 100 Changes.

Nov. 2007: Staff resubmit Section 100 Changes

Dec. 2007: Office of Administrative Law approves Section 100 Changes.

11. Increase fees to keep the board’s contingency fund solvent and maintain operations.

March 2007: Organization Development Committee reviews proposals and recommends approval.

April 2007: Board approves the proposal.

May 2007: Board releases language for the 45-day public comment period.

July 2007: Board adopts proposed changes for a 15-day comment period and if no negative comments are received board adopts regulations.

Aug. 2007: File submitted to the Department of Consumer Affairs to initiate Administration Review.

Oct. 2007: File submitted to the Office of Administrative Law for review.

Nov. 2007: Office of Administrative Law approves rulemaking.

Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.

Jan. 1, 2008: New fees take effect.

12. Secure regulatory standards for pharmacies that compound.

Dec. 2006: Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.

March 2007: Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.

May 2007: Licensing Committee holds detailed discussion on compounding regulations.

Sept. 2007: Licensing Committee forwards regulation proposal to the board for review.

Nov. 2007: Board releases language for the 45-day comment period.

Jan. 2008: Board held regulation hearing and considers written comments and oral testimony.

April 2008: Board votes to withdraw rulemaking.

Objective 3.3	Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked